

The Q-Net™ Monthly

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What's News

Q-Net would like to wish each of you "Happy Holidays" and a healthy and prosperous New Year.

A topic soon to be discussed in this newsletter will be the reprocessing of the endoscope's suction and air/water valves, both of which are integral components of the endoscope and without which the endoscope could not operate. Some manufacturers are recommending that these valves, also called "accessories," not be reprocessed in their automated reprocessors.

Editor-in-Chief

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What is 'Q-Net™'?

Q-Net™ is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

The main of **Q-Net™** is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net™ addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

FDA labeling of liquid sterilants

This editorial discusses the current labeling of liquid chemical sterilants (LCSs). Also discussed is the use of LCSs for reprocessing instruments in both the GI and OR settings.

Developing and marketing a liquid chemical sterilant (LCS) for reprocessing endoscopes is a more formidable task than often appreciated. The ideal LCS, among other factors, is safe to healthcare staff and the environment, relatively inexpensive, rapidly sporicidal, compatible with delicate instruments, non-foaming, and remains active in the presence of protein and organic soil. No currently marketed LCS satisfies all of these criteria.

Like with most drugs, for each of its benefits a LCS will typically have a salient shortcoming. For instance, LCSs that are rapidly sporicidal typically tend to be more corrosive, resulting in higher endoscope repair and maintenance costs.^{1,2} Despite their limitations, LCSs

are convenient, relatively fast-acting, and universally used to reprocess flexible endoscopes and other instruments.

Among other advantages including convenience, LCSs are routinely used to reprocess gastrointestinal (GI) endoscopes in or near the patient's procedure room.³ For healthcare facilities lacking a large inventory of endoscopes, the use LCSs avoids having to transport these expensive instruments to a remote central processing department (CPD), which can be costly and can remove the endoscope from service for a prohibitively long period of time.

But the convenience and cost-savings afforded by LCSs are not without a down side. Tension can develop between the healthcare facility's want to reprocess endoscopes as quickly as possible and patient safety. Two effective sterilization processes routinely used in CPDs are ethylene oxide (EtO) gas and steam autoclaves. The use of either for endoscope reprocessing is prohibitive: the former typically requires a 24 hour

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► Welcome new Q-Net subscribers! *The Q-Net™ Monthly* would like to welcome its international subscribers in Italy, Scotland, England, France, Brazil, Israel, Germany, Canada, Hong Kong, Singapore, Sultanate of Oman, Turkey, Australia, and New Zealand.

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aeration time before the endoscope can be returned to service for reuse, and the latter destroys the heat-sensitive and delicate materials used in the construction of fiberoptic flexible endoscopes.

LCSs can to some degree mollify this tension, providing healthcare staff with an effective 'point-of-use' reprocessing method that yields high-level disinfected endoscopes in less than 20 minutes. (Heating some LCSs, or altering their concentrations or pH, can enhance their biocidal properties and further reduce their immersion times.) To be sure, manufacturers relentlessly seek to develop and market LCSs labeled to 'sterilize' endoscopes (and other instruments) in less than an hour. Whether the Food and Drug Administration (FDA) will only for the second time in almost 15 years approve a LCS labeled for the 'sterilization' of endoscopes during an immersion time of less than an hour is unclear, although, in my opinion, not likely.

As with many biocidal agents, issues can arise with LCSs (eg, glutaraldehyde, ortho-phthalaldehyde, hydrogen peroxide, and peracetic acid) that warrant consideration and caution. For instance, the labels of most FDA-cleared LCSs, which some infection control and healthcare staff may find confusing,³ provide two instrument immersion times: one for *high-level disinfection*, and another, typically requiring a considerably longer immersion time (e.g., 3 to 10 hours), for *sterilization*.

Despite their dual label claims, it is my opinion that the FDA's original intent was to limit the use of LCSs intended for reprocessing flexible endoscopes only to high-level disinfection,^{4,5} having not fully anticipated that a LCS might be marketed exclusively for sterilizing endoscopes. Whereas sterilization is a multi-step process that includes, among other steps, cleaning, instrument wrapping, and specific quality controls such as the routine use of biological indicators (BIs), immersing an item in a LCS is virtually a single-step process.^{4,6} Confusing a multi-step and complete *sterilization* process with a LCS's single-step and limited *sporicidal* process can, in my opinion, result in a false level of assurance and increase the risk of patient infection.⁷

In summary, LCSs are convenient and easy to use but have several salient shortcomings that limit their effectiveness and reliability and call into question their current FDA-cleared labels that claim instrument *sterilization*. First, items reprocessed using a LCS lack a shelf-life, as they cannot be wrapped and therefore are susceptible to re-contamination during handling and storage. Second, in addition to conveying a higher sterility assurance level (SAL) than heat, EtO, and plasma sterilization processes,^{5,6} LCS-based processes lack essential quality controls and cannot be reliably monitored using BIs: The bacterial endospores on the BI's strip may be rinsed-off during its handling and immersion in the LCS, rendering the BI's results meaningless.⁸

Third, unlike pressurized steam that can diffuse through instruments' materials and patient debris and kill otherwise

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Does Cidex® OPA kill *B anthracis*?

A NURSE'S QUESTION: Last month's issue of *The Q-Net Monthly* (2001 Oct;7[10]) published that cleaning and high-level disinfecting endoscopes using 2% alkaline glutaraldehyde would be expected to destroy vegetative (non-sporulating) cells of *Bacillus anthracis*, the causative agent of anthrax. But it did not mention whether Cidex® OPA (0.55% ortho-phthalaldehyde), an alternative to glutaraldehyde, would also prevent anthrax infection following endoscopy. *Is Cidex® OPA expected to kill B anthracis?*

ANSWER: The labels of almost every FDA-cleared liquid chemical sterilant (LCS) used for reprocessing endoscopes include both a *high-level disinfection* and a *sterilization* claim (see main article, p. 21). Examples include 2% glutaraldehyde and 6% hydrogen peroxide. As discussed in the October and November 1999 issues of this newsletter, Cidex® OPA's label is unique and, unlike all other LCSs currently on the market, lacks a sterilization label claim. Its intended use is limited to high-level disinfection. (Nevertheless, according to its manufacturer [*Advanced Sterilization Products, or ASP, Irvine, CA*], data are available that show Cidex® OPA passes a standardized and well-recognized sporicidal test in 32 hours at room temperature.) This nurse's question that addresses the uniqueness of Cidex® OPA's label and focuses on whether its lack of a sterilization claim may hint at an inability to destroy *B anthracis* cells is insightful.

First, you may want to consider contacting Cidex® OPA's manufacturer directly (*ASP; www.sterrad.com; 800-STERRAD*) for more information on this germicide and specifically whether it destroys *B anthracis* cells.

Second, based on my research, Cidex® OPA, like 2% glutaraldehyde (and any other FDA-cleared high-level disinfectant), would prevent anthrax cross-infection, provided the *B anthracis* cells are in their vegetative (non-sporulating) state, as would be expected on an endoscope immediately following the procedure. (See last month's issue of *The Q-Net™ Monthly* for a more detailed discussion of *B anthracis* and the processes of 'sporulation' and 'germination.') Adherence to well-established endoscope reprocessing guidelines, such as those published by the *Society of Gastroenterology Nurses and Associates* (SGNA), has been shown to prevent disease transmission via endoscopes. *Note that no nosocomial cases of anthrax infection have to date been reported.*

If, however, the endoscope were not thoroughly cleaned and high-level disinfected immediately following the procedure, and it were allowed to remain unclean for several days or weeks, then unforeseen problems could arise. Indeed, the likelihood that any biocidal agent, including Cidex® OPA, 2% glutaraldehyde or ethylene oxide gas, when used in accordance with its respective labeling, would kill every *B anthracis* cell present on a contaminated instrument would decrease with time.

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inaccessible microorganisms, LCSs require direct contact with the microorganisms to be effective.⁶ LCSs are also viscous, which can limit their flow through narrow lumens and orifices.^{5,6,9} Further, the effectiveness of LCSs depends on the thoroughness of the cleaning process, which, if performed manually, is difficult to standardize, control, and monitor. An unclean instrument cannot be disinfected or sterilized. No doubt, the complex physical designs of most models of flexible endoscopes neither facilitate cleaning of every internal surface nor permit direct microbiological sampling, as required to validate the process's effectiveness.

The physical properties of LCSs and the designs of some complex instruments both contribute to limiting the effectiveness and anticipated reliability of LCS-based processes, compared to heat-based processes,⁴ as well as to increasing the probability that a flexible endoscope's internal surfaces may remain contaminated following immersion in the LCS. The need to re-design flexible endoscopes that provide direct access to every internal surface and can withstand the rigors of thermal sterilization cannot be overemphasized.

Fourth, unlike with heat and EtO gas (or plasma) sterilization, LCS-based processes uniquely require a final water rinse to remove potentially toxic residues (see Box articles on this page and p. 24). Indeed, the quality of the healthcare facility's water is often difficult to control and monitor. And if the final water rinse contains microorganisms, the instrument may become re-contaminated after chemical immersion.^{4,6,7} As a result, this essential final water rinse is, in my opinion, the Achilles' heel of current LCS-based processes. Multiple cases of patient infection and deaths linked to contaminated rinse water have been recently reported.⁹⁻¹¹ When properly maintained and replaced, bacterial filters can improve the water's microbiological quality and minimize the likelihood of instrument re-contamination during the final water rinse. But bacterial filters are not fail-safe, and their effectiveness after only a few uses has been reported to fail and permit the passage of bacteria.^{9,12-14}

In conclusion, due to the aforementioned limitations of LCSs and the challenges posed by complex instrument designs, claims that a LCS reliably 'sterilizes' flexible endoscopes are, in my opinion, suspect and warrant caution. *Independent data demonstrating that flexible endoscopes can be sterilized using LCSs (or any other method) have not been published.* Furthermore, according to the FDA, using LCSs to reprocess surgical instruments not damaged by heat (e.g., rigid endoscopes) is not recommended, due to "the inherent limitation of using (LCSs) for sterilizing medical devices."⁵

As a point of emphasis, sporicidal LCS-based processes are markedly less reliable than complete sterilization processes. Therefore, limiting the intended use of these LCS-based processes to high-level disinfection, especially if used to reprocess complex instruments, seems indicated and necessary for patient safety.^{4,6}

Rapicide™: 3 minute water rinses?

Question: Our endoscopy department is now trying Rapicide™, a 2.5% glutaraldehyde solution that, according to its label, achieves high-level disinfection in 5 minutes at 35° C. We read the package insert, and it is unclear to us how many water rinses (see Box article on p. 24) are required following chemical immersion. Could you please clarify this number for us?

Answer: I have reviewed Rapicide's™ (MediVators, Eagan MN) label, and indeed it does not specify the *number* of required water rinses following chemical immersion. It does, however, require that a "copious" volume of "fresh" (not reused) water be used for each rinse. Rapicide's™ label further states that "each rinse should be a minimum of three minutes in duration unless otherwise noted by the device manufacturer."

To be clear, Rapicide's™ rinsing instructions on its label indicates that the *number* of rinses following chemical immersion is to be determined by the automated endoscope reprocessor's (AER) manufacturer. (**Note:** Refer to the November 2000 issue of *The Q-Net™ Monthly* for more details on Rapicide™.)

To supplement the information included in its package insert and label, I read Rapicide's™ 510(k) Summary, dated August 2000, that MediVators submitted to the FDA. This summary states that "three separate rinses" may be required following chemical immersion. Combining Rapicide's™ labeling with its 510(k) Summary appears to suggest that, unless the AER manufacturer states otherwise, three rinses, each three minutes in duration, may be necessary.

Viewing the outcome of endoscopes immersed in a LCS as being high-level disinfected, rather than sterilized, also underscores to staff the importance of ensuring the endoscope has been pre-cleaned immediately after use and has been dried using 70% alcohol followed by forced air before storage, a step whose safety has been well-documented^{6,9,10,11} and which may be skipped if the intended use of the LCS is to achieve sterilization.^{15,16} Also, LCS-based processes that claim to 'sterilize' flexible endoscopes may paradoxically pose an increased risk of patient infection.^{7,15,16}

The FDA is therefore encouraged to caution users of the limitations of LCS-based processes,^{5,6} as well as to modify the current labels of LCSs from the immersion time required to achieve instrument *sterilization*, which can be a misleading claim, to the immersion time required to be *100% sporicidal*, the more valid label claim. The FDA is also encouraged to ensure LCSs be compatible with the instruments for which they are labeled to reprocess, lest the expense to repair endoscopes add to already escalating healthcare costs. ■ ►

Cidex® OPA: Are 3 rinses necessary?

Question: Our facility uses Cidex® OPA (see Box article on p. 22) to high-level disinfect transesophageal echocardiography (TEE) probes. We recently read that Cidex® OPA can discolor patients' skin, lips and mouths (see: *Materials Management*, August 2000, p. 10; and Cidex® OPA's package insert). *What measures can be taken to minimize the likelihood of Cidex® OPA staining the instrument and the patient's (and healthcare staff's) skin and tissues?*

Answer: In its memo dated May 1, 2001, *Advanced Sterilization Products (ASP, Irvine, CA)* re-emphasized to its Cidex® OPA users the critical importance of adhering strictly to this high-level disinfectant's specific chemical immersion time and water rinsing label instructions.

ASP recommends soaking all devices for 12 minutes in Cidex® OPA to achieve high-level disinfection. ASP further recommends immersing all devices for at least one minute in three separate water rinses, each fresh and of a large volume (eg, 2 gallons), discarding the used water after each separate rinse.

According to ASP, following these instructions will minimize, if not eliminate, the likelihood of residual Cidex® OPA Solution remaining on the device and staining and irritating the patient's mouth, skin or throat. Problems may arise when devices, particularly TEE probes, are immersed in Cidex® OPA for longer than one hour and/or are rinsed with water fewer than three times following chemical immersion.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD, Editor in Chief.* Please direct all correspondence to:

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